C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

[in Accordance with SMDA of 1990]

Aesculap Orthopilot® HTO module

April 22, 2002

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

Establishment Registration Number: 2916714

CONTACT: Georg Keller, Regulatory Affairs Manager
800/258-1946 x 5073 (phone)
610/791-6882 (fax)

TRADE NAME: Orthopilot® HTO module

COMMON NAME: Orthopilot® 2 Navigation Platform

DEVICE CLASS: Class II

PRODUCT CODE: HAW

CLASSIFICATION: 21 CFR Section 882.4560: Stereotaxic Instrument.

REVIEW PANEL: Neurology

INDICATIONS FOR USE

The Orthopilot® HTO module is designed to assist an orthopedic surgeon to navigate the two bone cuts to form the wedge for correction of the leg axis.

DEVICE DESCRIPTION

Orthopilot® HTO (High Tibia Osteotomy) module uses transmitters that are mounted to the patients bones, or are flexible to palpate landmarks and a camera to monitor the spatial location of those transmitters in relation to each other and the medical instruments. These locations are used to locate the centers of rotation of the femur head, ankle and knee. These measurements allow for greater accuracy than mechanical methods of ascertaining cutting angles. The HTO module is only a tool to navigate the instruments for the bone cuts. It is not linked to any specific implant.

PURPOSE FOR SUBMISSION

The purpose for this submission is to gain marketing clearance for the Aesculap Orthopilot® HTO module.

K021329

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. The Orthopilot® HTO module conforms to applicable ASTM and ISO standards.

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Orthopilot® HTO module is essentially identical to the Orthopilot® 2 Navigation Platform (subjected K013569), Kinamed Orthopilot® (K003347), Stryker Navigation System-Knee Module (K010204), Brainlab Vector Vision Knee (K010612).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 5 2002

Aesculap, Inc.
Mr. Georg Keller
Regulatory Affairs Manager
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K021327
Trade Name: Orthopilot® HTO Module
Regulation Number: 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: April 23, 2002
Received: April 26, 2002

Dear Mr. Keller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, (Misbranding by reference to premarket notification((21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 6382041 or (301) 4436597 or at its Internet address HYPERLINK http://www.fda.gov/cdrh/dsma/dsmamain.html http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K021327

Device Name: **Orthopilot® HTO module**

Indication for Use:

The Orthopilot® HTO module is designed to assist an orthopedic surgeon to navigate the two bone cuts to form the wedge for correction of the leg axis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021327

Prescription Use ✓ or Over-the-Counter Use _____

(per 21 CFR 801.109)